

Claims

1. A composition for treating sexual dysfunction by pulmonary inhalation, said composition comprising apomorphine, the apomorphine being in the form of a free
5. ~~base, pharmaceutically acceptable salt or ester.~~
2. A composition as claimed in claim 1, wherein the apomorphine is apomorphine hydrochloride.
- 10 3. A composition as claimed in either of the preceding claims, wherein the administration of the composition by pulmonary inhalation provides a C_{max} within 1 to 5 minutes of administration.
4. A composition as claimed in claim 3, wherein the C_{max} is at least 2ng/ml.
- 15 5. A composition as claimed in claim 4, wherein the C_{max} is at least 7ng/ml.
6. A composition as claimed in any one of the preceding claims, wherein the administration of the composition by pulmonary inhalation provides a terminal
20 elimination half-life of between 50 and 70 minutes.
7. A composition as claimed in any one of the preceding claims, wherein the administration of the composition by pulmonary inhalation provides a dose dependent $AUC_{0-\infty}$.
- 25 8. A composition as claimed in any one of the preceding claims, wherein the administration of the composition by pulmonary inhalation provides a dose dependent AUC_{0-t} .
- 30 9. A composition as claimed in any one of the preceding claims, wherein the administration of the composition by pulmonary inhalation provides a dose dependent C_{max} .

10. A composition as claimed in any one of the preceding claims, wherein the administration of the composition by pulmonary inhalation is not accompanied with the adverse side effects usually associated with the administration of apomorphine.
- 5 11. A composition as claimed in any one of the preceding claims, wherein the composition provides a dose of apomorphine of from about 100 to about 1600 micrograms of apomorphine or a pharmaceutically acceptable salt or ester thereof (based on the weight of the hydrochloride salt).
- 10 12. A composition as claimed in claim 11, wherein the dose is from about 200 to about 1600 micrograms.
13. A composition as claimed in claim 12, wherein the dose is from about 300 to about 1200 micrograms.
- 15 14. A composition as claimed in claim 13, wherein the dose is from about 400 to about 1000 micrograms.
15. A composition as claimed in any one of the preceding claims, wherein the sexual dysfunction is erectile dysfunction.
- 20 16. A composition as claimed in any one of claims 1 to 14, wherein the sexual dysfunction is female sexual dysfunction.
- 25 17. A composition as claimed in claim 15, wherein the erectile dysfunction is psychogenic.
18. A composition as claimed in claim 15, wherein the erectile dysfunction is organic.
- 30 19. A composition as claimed in any one of the preceding claims, wherein the composition is a dry powder composition.

20. A composition as claimed in claim 19, wherein the apomorphine has a mass median aerodynamic diameter of 10 μ m or less.
21. A composition as claimed in claim 20, wherein the mass median aerodynamic
5 diameter is 5 μ m or less.
22. A composition as claimed in any one of claims 19 to 21, wherein at least 90% of the apomorphine has a particle size of 10 μ m or less.
- 10 23. A composition as claimed in claim 22, wherein at least 90% of the apomorphine has a particle size of 5 μ m or less.
24. A composition as claimed in any one of claims 19 to 23, wherein the composition further comprises an additive material.
- 15 25. A composition as claimed in claim 24, wherein the additive material is provided in an amount from about 0.15% to about 5% of the composition, by weight.
- 20 26. A composition as claimed in either of claims 24 or 25, wherein the additive material is selected from the group consisting of leucine, magnesium stearate, lecithin, and sodium stearyl fumarate.
27. A composition as claimed in any one of claims 19 to 26, wherein the
25 composition further comprises an excipient material.
28. A composition as claimed in claim 27, wherein the excipient material is in the form of carrier particles having an average particle size of 40 to 70 μ m.
- 30 29. A composition as claimed in any one of claims 1 to 18, wherein the composition comprises a solution pMDI formulation including a propellant, a solvent and water.

30. A composition as claimed in claim 29, wherein the propellant is HFA134a and/or HFA227.
31. A composition as claimed in either of claims 29 or 30, wherein the solvent is
5 ethanol.
32. A composition as claimed in any one of claims 29 to 31, wherein said water is present in an amount from greater than 2% by weight to about 10% by weight of the solution pMDI formulation.
- 10 33. A composition as claimed in any one of claims 1 to 18, wherein the composition is a suspension pMDI formulation including a propellant.
34. A composition as claimed in claim 33, wherein the propellant is HFA134a
15 and/or HFA227.
35. A composition as claimed in claim 34, wherein the propellant includes about 60% by weight HFA134a and about 40% by weight HFA227.
- 20 36. A method of treating sexual dysfunction, the method comprising administering to a subject in need of such treatment a composition as claimed in any one of the preceding claims.
37. A method as claimed in claim 36, wherein the sexual dysfunction is male
25 erectile dysfunction.
38. A method as claimed in claim 36, wherein the sexual dysfunction is female sexual dysfunction.
- 30 39. A method as claimed in any one of claims 36 to 38, wherein the method does not cause the adverse side effects normally associated with the administration of apomorphine.

40. Use of apomorphine in the manufacture of a medicament for treating sexual dysfunction by pulmonary inhalation, wherein the medicament comprises a composition as claimed in any one of claims 1 to 35.

5 41. A use as claimed in claim 40, wherein the medicament does not cause the adverse side effects normally associated with the administration of apomorphine.

42. A dry powder inhaler device comprising a composition as claimed in any one of claims 1 to 28.

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43. A dry powder inhaler device as claimed in claim 42, wherein the inhaler is an active inhaler.

15 44. A dry powder inhaler as claimed in either of claims 42 or 43, wherein the inhaler is a breath actuated inhaler device.

45. A blister for use in a dry powder inhaler device as claimed in any one of claims 42 to 44, wherein the blister contains the composition.

20 46. A blister as claimed in claim 45, wherein the blister is a foil blister.

47. A blister as claimed in either of claims 45 or 46, wherein the blister comprises polyvinyl chloride or polypropylene in contact with the composition.

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